

## IN THE CLAIMS

Please revise the pending claims as follows:

1. **(Currently Amended)** A pharmaceutical composition comprising:

(a) ~~eplerenone in an amount from~~ about 25 mg to about 100 mg of particulate eplerenone having a D<sub>50</sub> particle size of about 25 to about 400 microns, and

(b) ~~one or more pharmaceutically acceptable carrier materials~~ about 0.5 to about 30 weight percent of one or more pharmaceutically acceptable disintegrants,

(c) about 5 to about 99 weight percent of one or more pharmaceutically acceptable diluents, and

(d) about 0.5 to about 25 weight percent of one or more pharmaceutically acceptable binding agents,

~~wherein at least one of the one or more carrier materials is a disintegrant, and~~

wherein the composition is an immediate release composition wherein at least about 80% of the eplerenone is dissolved in vitro within about 30 minutes in 0.1N HCl at 37°C, and

~~wherein the composition is an immediate release composition that substantially disintegrates within about 14 30 minutes after being inserted when placed in a water bath maintained at a persistent temperature of 37°C ± 2°C.~~

2. **(Previously Presented)** The pharmaceutical composition according to claim 1 wherein said composition comprises eplerenone in an amount of about 25 mg.

3. **(Previously Presented)** The pharmaceutical composition according to claim 1 wherein said composition comprises eplerenone in an amount of about 50 mg.

4. **(Previously Presented)** The pharmaceutical composition according to claim 1 wherein said composition comprises eplerenone in an amount of about 100 mg.

5. **(Currently Amended)** The pharmaceutical composition according to claim 1 wherein ~~said carrier material is cellulosic, and said cellulosic carrier material~~ at least one of the one or more diluents is selected from the group consisting of purified cellulose, microcrystalline cellulose, and alkyl celluloses and their derivatives and salts.

6. **(Canceled)**

7. **(Currently Amended)** The pharmaceutical composition according to claim ~~6~~1 wherein ~~said~~ at least one of the one or more binding agents ~~are~~ is selected from the group consisting of acacia, tragacanth, sucrose, gelatin, glucose, starch, celluloses, alginic acid, salts of alginic acid, magnesium aluminum silicate, polyethylene glycol, gums, polysaccharide acids, bentonites, polyvinylpyrrolidone, polymethacrylates, hydroxypropyl methylcellulose, hydroxypropyl cellulose, ethyl cellulose, and pregelatinized starch.

8. **(Canceled)**

9. **(Currently Amended)** The pharmaceutical composition according to claim ~~8~~1 wherein ~~said~~ at least one of the one or more diluents ~~are~~ is selected from the group consisting of lactose, starch, mannitol, sorbitol, dextrose, microcrystalline cellulose, dibasic calcium phosphate, sucrose-based diluents, confectioner's sugar, monobasic calcium sulfate monohydrate, calcium sulfate dihydrate, calcium lactate trihydrate, dextrates, inositol, hydrolyzed cereal solids, amylose, powdered cellulose, calcium carbonate, glycine, and bentonite.

10. **(Canceled)**

11. **(Currently Amended)** The pharmaceutical composition according to claim ~~10~~ 1 wherein ~~said at least one of the one or more~~ disintegrants ~~are~~ is selected from the group consisting of starches, sodium starch glycolate, clays, celluloses, alginates, pregelatinized corn starches, crospovidone, and gums.

12. **(Currently Amended)** The pharmaceutical composition according to claim 1 further comprising one or more pharmaceutically acceptable wetting agents, wherein said wetting agents or wetting agents are present at about 0.1% to about 15% of the total weight of the composition.

13. **(Original)** The pharmaceutical composition according to claim 12 wherein said wetting agents are selected from the group consisting of oleic acid, glyceryl monostearate, sorbitan mono-oleate, sorbitan monolaurate, triethanolamine oleate, polyoxyethylene sorbitan mono-oleate, polyoxyethylene sorbitan monolaurate, sodium oleate, and sodium lauryl sulfate.

14. **(Currently Amended)** The pharmaceutical composition according to claim 1 further comprising one or more pharmaceutically acceptable lubricants, wherein said lubricant or lubricants are present at about 0.1% to about 10% of the total weight of the composition.

15. **(Previously Presented)** The pharmaceutical composition according to claim 14 wherein said lubricants are selected from the group consisting of glyceryl behenate, magnesium stearate, calcium stearate, sodium stearates, stearic acid, hydrogenated vegetable oils, talc, waxes, Stearowet, boric acid, sodium benzoate, sodium acetate, sodium chloride, DL-Leucine, polyethylene glycols, sodium oleate, sodium lauryl sulfate, sodium stearyl fumarate and magnesium lauryl sulfate.

16. **(Original)** The pharmaceutical composition according to claim 1 comprising one or more pharmaceutically acceptable anti-adherents or glidants, wherein

said anti-adherent or anti-adherents or glidants are present at about 0.25% to about 10% of the total weight of the composition.

17. **(Previously Presented)** The pharmaceutical composition according to claim 16 wherein said anti-adherents or glidants are selected from the group consisting of talc, cornstarch, DL-Leucine, sodium lauryl sulfate, and magnesium, calcium and sodium stearates.

18-19. **(Canceled)**

20. **(Currently Amended)** The pharmaceutical composition according to claim 1 ~~comprising~~ wherein at least one of the one or more binding agents is hydroxypropyl methylcellulose.

21. **(Currently Amended)** The pharmaceutical composition according to claim 1 ~~comprising~~ wherein at least one of the one or more diluents is lactose.

22. **(Currently Amended)** The pharmaceutical composition according to claim 1 ~~comprising~~ wherein at least one of the one or more diluents is microcrystalline cellulose.

23. **(Currently Amended)** The pharmaceutical composition according to claim 1 ~~comprising~~ wherein at least one of the one or more disintegrants is croscarmellose sodium.

24. **(Currently Amended)** The pharmaceutical composition according to claim 1 ~~comprising~~ wherein at least one of the one or more diluents is lactose at about 5% to about 90% of the total weight of the composition; and  
microcrystalline cellulose at about 5% to about 90% of the total weight of the composition; and  
wherein at least one of the one or more binding agents is hydroxypropyl methylcellulose at about 0.5% to about 10% of the total weight of the composition.

25. **(Canceled)**

26. **(Currently Amended)** The pharmaceutical composition according to claim  $\pm$  24 comprising:

about 19 to about 40 weight percent of eplerenone;  
about 32 to about 52 weight percent of lactose;  
about 8 to about 28 weight percent of microcrystalline cellulose; and  
about 1 to about 8 weight percent of hydroxypropyl methylcellulose.

27. **(Currently Amended)** The pharmaceutical composition according to claim  $\pm$  24 comprising:

about 24 to about 35 weight percent of eplerenone;  
about 37 to about 47 weight percent of lactose;  
about 13 to about 23 weight percent of microcrystalline cellulose; and

~~about 2 to about 6 weight percent of croscarmellose sodium; and~~

about 2 to about 4 weight percent of hydroxypropyl methylcellulose; and

wherein at least one of the one or more disintegrants is croscarmellose sodium at about 2% to about 6% of the total weight of the composition.

28. **(Currently Amended)** The pharmaceutical composition according to claim  $\pm$  27 comprising:

about 28 to about 31 weight percent of eplerenone;  
about 41 to about 43 weight percent of lactose monohydrate;

about 17 to about 19 weight percent of microcrystalline cellulose;

about 4.5 to about 5.5 weight percent of croscarmellose sodium; and

about 2.5 to about 3.5 weight percent of hydroxypropyl methylcellulose.

29. **(Currently Amended)** The pharmaceutical composition according to claim  $\pm$  28 in the form of a coated or uncoated unit

dosage tablet wherein the uncoated tablet or the coated tablet prior to coating comprises:

- about 29.4 weight percent of eplerenone;
- about 42 weight percent of lactose;
- about 18.1 weight percent of microcrystalline cellulose;
- about 5 weight percent of croscarmellose sodium;
- about 3 weight percent of hydroxypropyl methylcellulose;
- about 1 weight percent of sodium lauryl sulfate;
- about 1 weight percent of talc; and
- about 0.5 weight percent of magnesium stearate.

30. **(Currently Amended)** The pharmaceutical composition according to claim  $\pm$  28 comprising:

- about 25 mg of eplerenone;
- about 34 mg to about 38 mg of lactose;
- about 14 mg to about 17 mg of microcrystalline cellulose;
- about 3 mg to about 6 mg of croscarmellose sodium;
- about 1 mg to about 4 mg of hydroxypropyl methylcellulose;
- about 0.25 mg to about 1.5 mg of sodium lauryl sulfate;
- about 0.25 mg to about 1.5 mg of talc; and
- about 0.1 mg to about 1 mg of magnesium stearate.

31. **(Currently Amended)** The pharmaceutical composition according to claim  $\pm$  28 comprising:

- about 50 mg of eplerenone;
- about 70 mg to about 73 mg of lactose;
- about 29 mg to about 33 mg of microcrystalline cellulose;
- about 6 mg to about 10 mg of croscarmellose sodium;
- about 4 mg to about 6 mg of hydroxypropyl methylcellulose;
- about 1 to about 2.5 mg of sodium lauryl sulfate;
- about 1 to about 2.5 mg of talc; and
- about 1 mg to about 1.5 mg of magnesium stearate.

32. **(Currently Amended)** The pharmaceutical composition according to claim ~~1~~ 28 comprising:

about 100 mg of eplerenone;  
about 141 mg to about 145 mg of lactose;  
about 60 mg to about 64 mg of microcrystalline cellulose;  
about 16 mg to about 18 mg of croscarmellose sodium;  
about 9 mg to about 11 mg of hydroxypropyl methylcellulose;  
about 3 mg to about 4 mg of sodium lauryl sulfate;  
about 3 mg to about 4 mg of talc; and  
about 1 mg to about 2 mg of magnesium stearate.

33. **(Original)** The pharmaceutical composition according to claim 1 in a unit oral dosage form.

34. **(Original)** The pharmaceutical composition according to claim 1, wherein said composition is in the form of a unit dosage tablet or capsule.

35. **(Original)** The pharmaceutical composition according to claim 1, wherein said composition is in the form of a unit dosage tablet.

36. **(Original)** The pharmaceutical composition according to claim 35 wherein the unit dosage tablet is a coated unit dosage tablet.

37. **(Original)** The pharmaceutical composition according to claim 1 in the form of an oral unit dosage tablet or capsule having a 25 mg, 50 mg or 100 mg dose of eplerenone.

38-44. **(Canceled)**

45. **(Original)** The unit oral dosage form of the pharmaceutical composition of claim 33 wherein the

composition is directly encapsulated or directly compressed into tablets.

46. **(Original)** The unit oral dosage form of the pharmaceutical composition of claim 33 wherein the composition is wet granulated and encapsulated or compressed into tablets.

47. **(Original)** The unit oral dosage form of the pharmaceutical composition of claim 33 wherein the composition is dry granulated and encapsulated or compressed into tablets.

48-56. **(Canceled)**

57. **(Original)** The method of treating a condition or disorder where treatment with an aldosterone receptor blocker is indicated, comprising orally administering a composition according to claim 1 to a patient in need of such treatment.

58. **(Original)** The method according to claim 57 wherein the condition or disorder is heart failure.

59. **(Original)** The method according to claim 57 wherein the condition or disorder is hypertension.

60. **(Original)** The method according to claim 57 wherein the condition or disorder is edema associated with liver insufficiency.

61. **(Original)** The method according to claim 57 wherein the condition or disorder is post-myocardial infarction.

62-72. **(Canceled)**



73. **(Currently Amended)** The pharmaceutical composition according to claim 1, wherein said composition substantially disintegrates within about 11 minutes ~~after being inserted and movably maintained~~ when placed in a water bath maintained at a ~~persistent~~ temperature of  $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$ .

74. **(Previously Presented)** The pharmaceutical composition according to claim 1, wherein said composition substantially disintegrates within about 10 minutes.

75. **(Previously Presented)** The pharmaceutical composition according to claim 1, wherein said composition substantially disintegrates within about 9 minutes.

76. **(Previously Presented)** The pharmaceutical composition according to claim 1, wherein said composition substantially disintegrates within about 6 minutes to about 11 minutes.

77. **(New)** The pharmaceutical composition according to claim 1, wherein said composition substantially disintegrates within about 20 minutes.

78. **(New)** The pharmaceutical composition according to claim 1, wherein said composition substantially disintegrates within about 14 minutes.